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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/130,887 08/07/98 GOLD

B 899-50283

EXAMINER

HM22/0508

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ART UNIT

PAPER NUMBER

1647

19

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/130,887

Applicant(s)

Gold

Examiner

Sharon L. Turner, Ph.D.

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-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-20-01
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-12 and 14-21 is/are pending in the application.
- 4a) Of the above, claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12, 14-18, 20, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. The Group and/or Art Unit of U.S. Patent application SN 09/130,887 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Technology Center 1600, Art Unit 1647.

Continued Prosecution Application

2. The request filed on 9-29-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09130887 is acceptable and a CPA has been established. An action on the CPA follows.

3. The amendment filed 2-20-01 has been entered and fully considered with the exception of the directed insertion to the specification at p. 1, line 14, before "(4)" as there does not appear to be such markings at p. 1, line 14. Clarification is required for entry.

4. Claim 13 is canceled. Newly submitted claim 19 has been renumbered claim 21 under Rule 1.126. Claims 6-12 and 14-21 are pending. Restriction is as set forth in Paper No. 15, mailed 12-15-00.

5. Applicant's election with traverse of Group III, claims 6-18 and 20 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the limitation "selecting (one) or more FK506 analogs comprises selecting one or more analogs that do not substantially inhibit FKBP-12 rotamase activity when administered to a patient at dosage levels up to about 100 mg/kg body weight/day," as recited in claim 19, is not a further method step but rather an inherent pharmacological characteristic of the selected FK-506 analog.

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This argument has been fully considered but is not persuasive. The examiner understands applicants arguments to assert that FK-506 analogs inherently do not substantially inhibit FKBP-12 rotamase activity when administered to a patient at dosage levels up to about 100 mg/kg body weight/day. However, the examiner finds no such evidence of record to support this assertion. In contrast, it appears that the parent claims are directed to FK506 analogs which differentially bind FKBP-12 and differentially affect rotamase activity. Thus, it is presumed that the FK506 analogs of the invention differentially affect rotamase activity. Such effects may not necessarily be based upon the analogs individual FKBP-12 binding characteristics. Accordingly, it appears that the limitation serves to recite an additional step which is required for the selection of particular analogs (i.e., administration to patients), including evaluation of rotamase activity in patients which is not inclusive of binding. As the step is not encompassed by the parent claim, it is not further limiting, constitutes a new method and presents additional search burden to the examiner.

The requirement is still deemed proper and is therefore made FINAL.

6. Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Drawings

7. The drawings submitted with this application were declared informal by applicant. Accordingly they have not been reviewed by a draftsman at this time. When formal drawings

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are submitted, the draftsperson will perform a review. Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.

Specification

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

9. It is noted that the specification at p. 17, line 23 refers to US Patent 5,654,332 however the examiner has been unable to obtain or locate such patent. As such the material appears to be an improper incorporation by reference. Applicant is requested to review the reference for typographical error or to alternatively submit the patent to the examiner for review.

Claim Objections

10. Claims 7-11, 14 and 16-18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims fail to further limit a non-binding FKBP-12 analog because the recited characteristics are not of non-binding FKBP-12 analogs but to analogs which bind FKBP12 at a particular affinity. In addition, selection irrespective of rotamase activity and selecting for rotamase activity does not further limit the compounds or method steps of claim 6 since there is no selection based on rotamase activity and the compounds are not further defined, thus the claims do not appear to further limit the compounds or selecting steps.

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Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitations “significantly inhibit” and “low” however such terms are vague and indefinite because the artisan cannot readily discern the degree of inhibition which is required to fall within the scope of the claim.

13. Claims 8-10, 14 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite non-binding FKBP-12 analogs which bind FKBP12 at a particular affinity. The analogs are indefinite because they are defined by a contradictory statement. The artisan cannot discern those analogs which are within the scope of the claim.

14. Claims 7, 11 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7, 11 and 18 recite FK506 analogs selected based upon rotamase activity. However, the method steps do not stipulate a selection based upon rotamase activity and thus the method steps do not result in the selection of compounds with the

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claimed characteristics. The method is thus indefinite with respect to the steps and compounds to be identified.

15. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because claim 20 is dependent upon canceled claim 13.

Claim Rejections - 35 USC § 102 or 103

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

17. Claims 6-12, 14-18 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Steiner et al., US Patent No. 5,801,197, Sept. 1, 1998, filed May 13, 1996.

Steiner et al., teach FK506 analogs characterized by their ability to bind (or not bind) FKBP12, inhibit rotamase activity and stimulate neurite outgrowth in DRG cultures, see in particular column 7, lines 1-6 and Tables I-IV. Thus, the reference teachings anticipate the claimed methods as the method steps are performed in the analysis and identification of the compounds of the '197 patent.

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18. Claims 6-12, 14-18 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Armistead et al., US Patent No. 5,717,092, Feb. 10, 1998, filed Mar. 29, 1996.

Armistead et al., teach evaluation of candidate agents for the properties of FKBP12 binding, inhibition of rotamase activity and the ability to stimulate neurite outgrowth, see in particular column 15, lines 25-31, 49-67, and Examples 9-11. Thus, the reference teachings anticipate the claimed methods as the method steps are performed in the analysis and identification of the compounds of the '092 patent.

19. Claims 6-12, 14-18 and 20-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Steriner et al., Nature Medicine 3(4):421-28, April 1997.

Steriner et al., teach evaluation of FK506 analogs by the properties of FKBP12 binding, inhibition of rotamase activity and the ability to stimulate neurite outgrowth, see in particular abstract, figure legend of Table 1, p. 422, column 2 through p. 423, column 1, p. 424, column 2, lines 3 through p. 425, column 1, line 10 and Table 4. Thus, the reference teachings anticipate the claimed methods as the method steps have been performed in the analysis of the FK506 analog compounds of Steiner et al.

Status of Claims

20. No claims are allowed.

21. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice

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published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
May 1, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud